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No. 96-

IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

COLLAGEN CORPORATION,
Cross-Petitioner,

v.

IRENE M. GREEN, *et al.*,
Cross-Respondents.

Conditional Cross-Petition for Writ of Certiorari to the Supreme Court of Pennsylvania

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CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) preempts a common law claim that the manufacturer of a medical device made fraudulent submissions to the Food and Drug Administration in connection with the agency's premarket approval process under 21 U.S.C. § 360e(c).*

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* The parties below, in addition to cross-petitioner Collagen Corporation, were Irene M. Green, Martin Green, and Richard L. Dolsky. Collagen Corporation has no parent corporation and no non-wholly owned subsidiaries.

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Collagen Corporation ("Collagen") respectfully cross-petitions for a writ of certiorari to review the judgment of the Supreme Court of Pennsylvania in this case. If the Court grants the petition in No. 96-1340, this cross-petition should be granted as well. If the Court denies that petition, this cross-petition should be denied.

OPINIONS BELOW

The opinion of the Pennsylvania Supreme Court is reported at 685 A.2d 110 (1996). Pet. App. 1-17 ("Pet. App." refers to the appendix to the petition in No. 96-1340). The opinions of the Pennsylvania Superior Court (Pet. App. 18-32) and the Court of Common Pleas of Montgomery County (Pet. App. 33-34) are not reported.

JURISDICTION

The judgment of the Supreme Court of Pennsylvania was entered on November 22, 1996. Pet. App. 15. Irene M. Green and Martin Green filed a petition for a writ of certiorari (No. 96-1340) on February 20, 1997, and the petition was docketed on that day. This conditional cross-petition is filed pursuant to Rule 12.5 of this Court. The Court's jurisdiction is invoked under 28 U.S.C. § 1257.

STATUTE INVOLVED

21 U.S.C. § 360k(a) in pertinent part provides:

> . . . no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

STATEMENT

The facts and proceedings below are discussed in full in Collagen's brief in response to the petition filed in No. 96-1340 ("Collagen Resp."). In summary, cross-respondents Irene M. Green and Martin Green sued Collagen on various tort law theories, claiming injury resulting from treatment with Zyderm®, a medical device manufactured by Collagen that has been found safe and effective and approved for marketing by the Food and Drug Administration ("FDA") pursuant to the statutory premarket approval ("PMA") process under 21 U.S.C. § 360e(c).

The Pennsylvania Supreme Court held that most of the Greens' claims are barred by the MDA preemption statute,

21 U.S.C. § 360k(a). Pet. App. 11-12, 14. The court ruled that two categories of claims, however, are not barred. First, the court held that the Greens could pursue their claim that Collagen had failed to conduct post-approval studies as required by the FDA. *Id.* at 14 & n.8. Collagen does not seek review of that ruling.

Second, the court held that the Greens are entitled to bring a laundry list of claims that allege, "in essence, that [Collagen] fraudulently completed the premarket approval process." Pet. App. 12-13 n.7. This ruling, which permits litigation of common law claims alleging that a manufacturer defrauded the FDA in the course of the PMA process, is the subject of this conditional cross-petition.

The Green's claim that Collagen defrauded the FDA is factually baseless. In 1991, ten years after granting Zyderm premarket approval, the FDA itself, in the face of similar accusations, carefully reviewed the record and reconfirmed its finding that Zyderm is safe and effective. *See* Collagen Resp. 4. But the point of this cross-petition is that the MDA preemption statute does not authorize or permit the comprehensive judicial intrusion into the agency's PMA process that litigation of such claims would entail.

REASONS FOR GRANTING THE CROSS-PETITION

As Collagen explained in its response to the petition in No. 96-1340, this Court should grant certiorari there to determine the application of the MDA preemption statute to cases involving medical devices that the FDA has found to be safe and effective and has approved for marketing pursuant to the PMA process. If that petition is granted, this cross-petition should be granted as well. Cases like this, involving tort claims with respect to medical devices that have "run[] the gauntlet of the PMA process," *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2254 (1996), commonly encompass a claim that the manufacturer de-

frauded the FDA during the course of that process. *See, e.g., Mitchell v. Collagen Corp.*, 67 F.3d 1268 (7th Cir. 1995), *vacated and remanded*, 116 S. Ct. 2576 (1996); *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993); *Mears v. Marshall*, 130 Or. App. 390, 905 P.2d 1154 (1995), *vacated and remanded*, 324 Or. 130, 921 P.2d 966 (1996). In determining the proper scope of MDA preemption, the Court should consider the application of the statute to these frequently asserted claims of "fraud on the FDA."

The court below reasoned that "[s]uch claims are cognizable for they mirror FDA prohibitions against fraud." Pet. App. 12-13 n.7. The court did not identify any specific regulation actually setting forth such a prohibition, but Collagen has no doubt that the regulations governing the PMA process either explicitly or implicitly forbid fraudulent submissions. That fact, however, should not insulate common law claims of "fraud on the FDA" from preemption.

Although the court below did not say so, it may have believed that its ruling on this issue was dictated by *Lohr*. If so, the court was misreading this Court's decision. In *Lohr*, this Court held that 21 U.S.C. § 360k(a) does not bar state law tort claims alleging that a medical device has been manufactured and distributed in violation of FDA regulations. *Lohr*, 116 S. Ct. at 2255-56. The Court reasoned that the state requirements embodied in such claims are not "different from, or in addition to, any [federal] requirement," within the meaning of the MDA preemption statute. But claims of "fraud on the FDA" are of a wholly different species.

The Court's decision in *Lohr* means, for example, that if a manufacturer negligently fails to comply with the FDA's requirements relating to quality controls or label-

ing, state law can, in effect, enforce those requirements. This is, at least in theory, a simple matter: the FDA's requirements with respect to quality controls or labeling are taken as a given; the court determines as a factual matter whether those requirements were met; if they were not met, and the failure to meet them caused injury, the court enforces the requirements through an award of damages. Nothing in this process impairs the integrity of the federal regulatory scheme. To the contrary, such a process, if conducted with a proper understanding of the actual federal requirements, could serve to support and reinforce FDA's informed judgment concerning how the particular medical device should be manufactured and distributed.

Claims of "fraud on the FDA" are designed to have, and if recognized will have, precisely the opposite result, The thrust of such claims is that (1) had the FDA known the "true" facts, either it would not have found the medical device to be safe and effective or, in approving the device for marketing, it would have imposed different requirements with respect to such matters as manufacturing or labeling, and (2) therefore the court itself, or the jury, should replace the FDA's actual determinations either with a determination that the device in fact is not safe and effective or by imposing different or additional requirements that the manufacturer in fact did not meet. Such a process supplants the FDA and destroys the integrity of the federal regulatory scheme. Nothing could be more contrary to both the letter and the spirit of 21 U.S.C. § 360k(a).

It therefore is not surprising that every court that specifically addressed this issue prior to *Lohr* held that the FDA preemption statute bars tort claims alleging "fraud on the FDA." As the Third Circuit explained, such claims

> encourage the district court to review the PMA application [the manufacturer] submitted to the FDA. This inquiry could ultimately require that a court determine whether the information [the manufac-

> turer] submitted was truthful, whether it was complete, whether FDA procedures sufficed to avoid a material misrepresentation, and whether the FDA should have or would have approved the device despite the misrepresentations. In sum, this claim requires a court, applying state law, to perform the same functions initially entrusted to the FDA.
>
> Section 360k does not permit such a searching state inquiry into the inner workings of FDA procedures. Congress allocated the FDA responsibility to design and manage a process which would result in approval of the safest and most effective medical devices possible. Congress also assigned the FDA the responsibility to approve or disapprove of applications to market medical devices. Under § 360k, states may not impose different requirements and thereby reach a different conclusion than the FDA.

Michael, 46 F.3d at 1329. The First Circuit similarly noted:

> Surely, where the FDA was authorized to render the expert decision on [the manufacturer's] use and labeling, it, and not some jury or judge, is best suited to determine the factual issues and what their effect would have been on its original conclusions. Further, if the court erred, and incorrectly posited the effect on the FDA's use and labeling decision, this would impose a state requirement "which is different from, or in addition to, any requirement applicable . . . to the device."

King, 983 F.2d at 1140 (Aldrich and Campbell, JJ., concurring); *see also, e.g., Mitchell,* 67 F.3d at 1284; *Reeves v. AcroMed Corp.,* 44 F.3d 300, 306 (5th Cir.), *cert. denied,* 115 S. Ct. 2251 (1995); *Mears,* 137 Or. App. at 406-07, 905 P.2d at 1166-67.

If this Court grants review in this case, it should correct the lower court's error in allowing the Greens to claim "fraud on the FDA." A common law judge and jury cannot be allowed to displace the FDA and its

statutory PMA process by substituting their own views concerning whether and how a medical device is to be manufactured and marketed. The court below glossed over this important concern, which lies at the very heart of the MDA preemption statute.

CONCLUSION

If the petition for a writ of certiorari is granted in No. 96-1340, this cross-petition also should be granted. If that petition is denied, the cross-petition also should be denied.

Respectfully submitted,

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